DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. John Willis
Director of Regulatory Affairs
Byrne Medical Inc.
3150 Pollok Dr.
CONROE TX 77303

NOV - 8 2010

Re: K102581
Trade/Device Name: DEFENDO™ Disposable Suction Valve for GI Endoscopes
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC, FDF
Dated: September 7, 2010
Received: September 9, 2010

Dear Mr. Willis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name: DEFENDO™ Disposable Suction Valve for GI Endoscopes

Indications for Use:

The DEFENDO™ Disposable Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102581

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510(k) Summary of Safety and Effectiveness Data

Summary of Safety and Effectiveness Data

The Byrne Medical, Inc., DEFENDO™ Disposable Suction Valve and predicate device (Olympus® MH-443 Suction Valve, K001241) are in Class II, 21 CFR 876.1500 with Advisory Committee of Gastroenterology/Urology.

The predicate device Olympus® - Suction Valve (K001241) is manufactured by Olympus® Optical Co. Ltd. Tokyo, Japan.

The Byrne Medical, Inc., DEFENDO™ Disposable Suction Valve has been determined to meet the equivalence decision making process as detailed by the "510(k) Substantial Equivalence Decision-Making Process Flowchart".

Table 14-1: Comparison of features and principles of operation between the DEFENDO™ Disposable Suction Valve and Predicate Device (Olympus®MH-443 Suction Valve, K001241)

Characteristic	Byrne Medical	Olympus®	Same?
Part number	100305	MH-443	N/A
Trade Name	100305 DEFENDO™ Disposable Suction Valve	Olympus® EVIS EXERA Colonovideoscopes	N/A
510(k) Doc. Number	This submission	K001241	N/A
Product Code	KOG	FDF	No
Regulation Number	876.1500	876.1500	Yes
Class	II	II	Yes
Review Advisory Committee	Gastroenterology/Urology	Gastroenterology/Urology	Yes
Indications for use	The DEFENDO™ Disposable Suction Valve is intended to be used to control the Suction function on an endoscope during a GI endoscopic procedure.	The Olympus® Suction valve is intended to be used to control the Suction function on an Olympus ®endoscope during a GI endoscopic procedure.	Yes
Sterile	Yes	No, user must sterilize	No
Single Use	Yes	No, re-sterilize, re-use	No
Compatible Endoscope(s)	Olympus® 140/160/180/240/260 series endoscopes	Olympus® 140/160/180/240/260 series endoscopes	Yes
Patient Population	Male/Female, Pediatric to Adult	Male/Female Pediatric to Adult	Yes
Reusable or disposable	Disposable	Reusable	No

Testing:
The DEFENDO™ Disposable Suction Valve testing was conducted under FDA recognized standards.

Similarities and Differences:

Indications for Use
Both products are attached to the Suction cylinder of the endoscope. When the valve is depressed, suction function on the endoscope is activated allowing for the suctioning of fluid through the stem of the valve where it flows into the Suction Pump Canister.

The DEFENDO™Disposable Suction Valve and its predicate have the same regulation number and class, the same patient population and environment of use.

Neither the predicate nor the Byrne Suction valve come in direct contact with the patient. Fluid flow is one way, away from patient..

Comparative Testing

Bench testing for the 100305 Suction Valve

Background:

Bench testing is performed to confirm that the disposable BMP-215 DEFENDO™ Disposable Suction Valve is equivalent to the predicate Olympus® MH-443 Suction Valve.

Acceptance criteria:

Connection to the endoscope	The valve must connect to the endoscope by aligning valve with port and pressing down. Must not be cumbersome to attach.
Priming time to Suction Canister	The device must be comparable to the predicate device in terms of being able to supply water within a reasonable time frame (priming time).
Material Quantity Removed	The device must be comparable to the predicate device in terms of the amount of water removed in the defined time frame.
Spring Force & Displacement	The device must be comparable to the predicate device in terms of force required to activate the button.
No sharp edges	The device must not be capable of snagging or piercing a nitrile glove if the wearer rubs his or her gloved fingers over any surface of the device.

Procedure:

Materials and Equipment	
Olympus® 160 series endoscope	Nitrile Glove
Olympus® MH-443 Suction Valve	Stopwatch
Byrne Medical BMP-215 Suction Valve	Endo SmartCap
IMADA Force Gage	Olympus Suction Pump
Water Basin with water	Scale
Suction Tube for Suction Pump	

1. To test connection to the endoscope: Aligned BMI suction valve with port and pressed down. Recorded observations on the ease of use as compared to predicate.

2. To test for priming time: Test set-up replicated a typical GI system for procedures by attaching the suction valve into the port and using a sterile water bottle with a new SmartCap. Placed the distal tip in a water bath. Turned the suction pump on, set the stop watch to 0. Then depressed the suction button and quantify the time it takes for the water to travel from the distal tip of the endoscope to the suction canister.

3. To test for material quantity removed: Drained water from scope and removed water from suction canister, weighed empty canister and zeroed scale, returned canister to suction pump and replaced cap on canister, inserted endoscope into water basin, turned suction pump on, set stop watch to 0, depressed suction valve firmly with finger over the complete button head and held for 30 seconds. At the end of the 30 seconds, removed finger from button, removed canister from suction pump and weighed the amount of net water suctioned through the scope. Determined if the predicate and the disposable have comparable material quantity removal.

4. To test for spring force: Attached the suction valve into the port and fixtured the port channel under the IMADA force gage. Used a flat attachment on the force gage to be able to depress the suction valve. Recorded the force/ displacement readings to create a curve.

5. To test for sharp edges: Placed nitrile gloves on tester's hand and attached the suction valve to the port. Touched every part of valve, especially the spring area. Recorded observations on snagging or ripping of glove.

6. To test connection to the endoscope: Align BMI suction valve with port notches and press down. Record observations on the ease of use.

7. To test for priming time: Test set-up replicated a typical GI system for procedures by attaching the suction valve into the port and the suction line to the suction pump. Place the distal tip in a water bath. Turn the suction pump on and set the stop watch to 0. Then depress the suction button and quantify the time it takes for the water to travel from the distal tip of the endoscope to the suction canister.

8. To test for material quantity removed: Drain water from the scope and remove water from the suction canister, weigh empty canister and zero scale, return canister to suction pump and replace cap on canister, insert endoscope into water basin, turn suction pump on, set stop watch to 0, depress suction valve firmly with finger over the complete button head and hold for 30 seconds. At the end of the 30 seconds, remove finger from button, remove canister from suction pump and weigh the amount of net water suctioned through the scope. Determine if the predicate and the disposable have comparable material quantity removal.

9. To test for spring force and displacement: Attach the suction valve into the port and fixture the endoscope body under the IMADA force gage. Use a flat attachment on the force gage to be able to depress the suction valve. Record the force and displacement readings to compare products.

10. To test for sharp edges: Tester is to put on nitrile gloves and attach the suction valve to the port. Ask tester to touch every part of valve, especially the spring area. Record observations on snagging or ripping of glove.

Results:

1. Connection to the endoscope

Olympus (predicate)	BMI 100305
Smooth	Smooth
Smooth	Smooth
Smooth	Smooth
Smooth	Smooth
Smooth	Smooth
Smooth	Smooth
Smooth	Smooth
Smooth	Smooth
	Smooth
	Smooth
Average	Average
Smooth	Smooth

Result: Pass

The force required to connect the BMI suction valve (100305) and the ease of installation was similar to the predicate (Olympus® MH-443). Alignment with the port notches was comparable. Test results verify that the BMI suction valve (100305) is substantially equivalent to the predicate device.

2. Priming time:

Olympus (predicate)	BMI 100305
4.19	3.97
4.19	3.93
4.21	4.13
4.32	4.09
4.19	4.00
3.82	3.71
4.21	3.59
4.12	3.97
	3.91
	3.97
Average	**Average**
4.16	**3.92**
Standard Deviation	**Standard Deviation**
0.147	**0.163**

Result: Pass
The test was performed to establish the time that the water took to travel from the water reservoir to the distal tip of the endoscope. The results indicate that there is no significant difference between the two units. The BMI suction valve is substantially equivalent to the predicate (MH-443).

3. To test for material quantity removed

Eight BMP-215 and eight MH-443 Suction Valves were tested for suction ability by placing an endoscope into a filled water basin. Suction Valves were depressed with finger over hole in valve head and suction was performed for thirty seconds ten times each for each of the eight valves. The results are presented below:

Olympus MH-443 Suction Valve									
	Sample								
	Test	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Material Removed In Grams	1	534.4	541.2	540.0	545.4	544.5	540.8	543.3	545.7
	2	533.3	537.5	522.8	523.7	525.8	516.3	510.0	515.3
	3	539.6	552.7	531.6	522.9	521.3	513.6	509.8	513.0
	4	553.1	545.1	540.0	520.5	523.2	515.1	513.3	509.6
	5	554.4	541.8	522.8	527.2	532.0	517.8	514.2	511.0
	6	556.4	539.1	531.6	524.0	529.4	516.8	511.1	512.8
	7	551.1	548.0	540.0	534.7	524.2	520.0	520.6	510.1
	8	553.5	534.3	522.8	524.2	517.7	515.6	517.1	522.5
	9	550.3	544.5	531.6	529.8	507.9	527.0	520.8	529.3
	10	546.8	527.9	540.0	536.5	513.2	515.4	505.7	512.4
Average		547.3	541.2	532.3	528.9	523.9	519.8	516.6	518.2
								Grand Average	528.5
								Standard Deviation	13.61

Byrne Medical Suction Valve									
	Sample								
	Test	1	2	3	4	5	6	7	8
Material Removed in Grams	1	540.5	536.9	535.7	533.2	538.8	535.8	542.0	539.5
	2	511.6	505.4	509.8	514.9	510.9	518.5	507.7	506.2
	3	501.6	508.2	507.8	504.8	520.3	505.5	503.1	509.2
	4	520.4	515.4	511.2	507.1	520.3	524.9	499.6	509.3
	5	517.4	508.0	510.0	511.4	515.9	506.0	504.2	493.4
	6	511.1	506.8	509.5	498.7	507.0	520.2	526.4	489.9
	7	483.9	510.2	516.2	501.6	504.4	506.9	509.1	508.6
	8	494.6	508.7	522.4	519.9	513.3	514.6	517.4	511.3
	9	510.0	508.3	498.0	519.6	504.0	512.2	504.9	504.2
	10	511.6	509.9	509.6	509.1	510.2	504.7	510.8	510.4
Average		510.3	511.8	513.0	512.0	514.5	514.9	512.5	508.2
								Grand Average	512.2
								Standard Deviation	11.25

Result: Pass

The test was performed to determine the amount of material that can be removed when engaging the device. Looking at the upper and lower limit of delivery (for 30 seconds) yielded a difference of +23g and -8g versus the BMI suction valve. This equates to < 4.5% difference for the worst case view. It should be noted that doctors typically operate suction for only 5-10 seconds at a time. As a result this would further reduce any perceived variation to less than 3.3% difference (528.5/30*10-512.2/30*10=176.2-170.3= 5.9g; 5.9/176.3= 3.3%). The BMI unit additionally shows improved repeatability as compared to the predicate (SD of 11.25 versus 13.61) which will further reduce variability.

4. Spring force and Displacement

Olympus (predicate)		BMI 100305	
Force (lb)	Displacement (in)	Force (lb)	Displacement (in)
2.02	0.190	2.98	0.193
2.04	0.191	2.51	0.198
2.16	0.188	2.86	0.200
2.07	0.187	2.92	0.194
2.05	0.181	2.97	0.200
2.21	0.186	3.02	0.199
1.95	0.183	2.94	0.194
2.15	0.197	2.90	0.196
		2.56	0.194
		2.96	
Average		**Average**	
2.0813	**0.1876**	**2.862**	**0.1962**
Standard Deviation		**Standard Deviation**	
0.086	**0.005**	**0.178**	**0.003**

Result: Pass

The physics formula for the force of the spring is Hooke's Law F=-kx, where F is force, k is spring constant and x is displacement. The spring constants of the predicate and BMI suction valve were determined by using a force gage with a displacement gage. The measured values show a slight difference between the two devices, however, these differences cannot be perceived in blind tests by the tester or other selected parties (3 additional people). The BMI suction valve force and displacement is substantially equivalent to the predicate (MH-443).

5. Sharp edges

Olympus (predicate)	BMI 100305
Pass	Pass
Pass	Pass
Pass	Pass
Pass	Pass
Pass	Pass
Pass	Pass
Pass	Pass
Pass	Pass
	Pass
	Pass
Average	Average
Pass	Pass

Result: Pass
Testing showed that the BMI Suction valve does not pinch, cut, or tear the nitrile gloves. Test results confirm that BMI Suction Valve (100305) effectively attached and removed from corresponding port without posing a pinch, cut, or tear hazard to a healthcare professional's PPE (gloves). The BMI suction valve is substantially equivalent to the predicate (MH-443) for potential for tearing a glove.

Conclusion:
Based on these results, we have determined that the Byrne Medical DEFENDO™ Disposable Suction Valve is substantially equivalent to the Olympus MH-443 Suction Valve.